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EXAMINER
MARSCHER, A

ART UNIT	PAPER NUMBER
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1807

DATE MAILED:

11/16/93

18N1/1116
NEEDLE & ROSENERG, P.C. SUITE 1200
THE CANDLER BUILDING
127 PEACHTREE STREET, N.E.
ATLANTA GEORGIA 30303

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 8/12/93 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 44-47 and 60-62 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-43 and 48-59 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 44-47 and 60-62 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Applicants' arguments filed 8/12/93 have been fully considered but they are not deemed to be persuasive to overcome the previously applied rejections. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

Claim 62 contains NEW MATTER as a result of the phrase "the presence of...indicating a more malignant phenotype". This phrase discloses the correlation between said "presence" and a "more malignant phenotype". Applicants cite page 23, lines 14-27, as supporting disclosure. This is non-persuasive because said page 23 citation describes the measurement of levels of the amounts of mRNAs in a series of cell lines but there is absolutely no evaluation or correlation to the amount of malignancy in various cell phenotypes. In other words and more specifically, there is no determination or correlation supporting

the limiting word "more" cited in the last line of claim 62 in the phrase "more malignant phenotype". Clearly "more" in claim 62 discloses some comparison between different malignant phenotypes. None of the cell lines discussed on page 23 are therein characterized so as to compare malignancies and therefore the presently pending claim 62 contains NEW MATTER.

Claim 62 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 44-47 and 60-62 are rejected under 35 U.S.C. § 101 because the claimed invention lacks support for the disclosed utility directed to the diagnosis or evaluation of cancer in a human.

The rejection of claim 62 is included herein in anticipation of the removal of the NEW MATTER as summarized above leaving the remaining claim limitations directed to diagnosis as for example claim 44. Each of the exhibits are discussed as follows:

1. This reference lacks citation of even a single negative control and thus is non-persuasive regarding correlative evidence.

2. This reference lacks citation of even a single negative control and thus is non-persuasive regarding correlative evidence.

3. This reference lacks citation of even a single negative control and thus is non-persuasive regarding correlative evidence.

4. The title of this reference discloses that evidence therein supports a correlation between risk of cancer and c-erbB-2 amplification and not cancer diagnosis which is the utility cited for the instant invention.

5. This reference summarizes in the abstract that correlation to cancer is based on immunoassay results and not gene amplification as given in the instant invention.

6. This reference summarizes in the abstract that correlation to cancer is based on immunoassay results and not gene amplification as given in the instant invention.

7. This reference discloses on page 4332, second column, the first paragraph in the section entitled "MATERIALS AND METHODS" that every patient that participated in the study had breast cancer. This is non-persuasive due to a lack of negative controls regarding correlative evidence.

8. This reference discloses on the first page of the exhibit (page numbers are not shown in the copy on file), second column, last line of the first paragraph, that every patient that participated in the study had operable cancer. This is non-persuasive due to a lack of negative controls regarding correlative evidence.

9. This reference summarizes in the abstract that correlation to cancer is based on immunoassay results and not

gene amplification as given in the instant invention.

10. This reference summarizes in the abstract that correlation to cancer is based on immunoassay results and naot gene amplification as given in the instant invention.

11. This reference summarizes in the abstract that correlation to cancer is based on immunoassay results and naot gene amplification as given in the instant invention.

12-16. These are review references that draw conclusions but supplies no evidence.

17. The abstract discusses erbB-2 amplification is tumors but does not define what controls were evaluated. Several cell lines are reported as demonstrating mRNA levels from 4-128 fold over controls. Such cell lines evidence however is in-vitro evidence lacking yet a direct connection with in-vivo evidence as required for the stated utility for the instant invention.

In summary, the exhibits supplied as evidence are all deficient as noted above and the rejection is reiterated and maintained as set forth in the previous office action mailed 2/9/93.

Claims 44-47 and 60-62 are allowable over the prior art of record because of reasons of record.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of

automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is either (703) 308-4227 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Am

A. MARSCHEL:am

November 15, 1993

AMELIA BURGESS YARBROUGH
PRIMARY EXAMINER
ART UNIT 1807